

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of Orphan Products Development(HF-35)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

January 12, 1994

RECEIVED JAN 18 1994

Therapeutic Antibodies, Inc.
Attention: Mr. John S. Cipriano, M.S. R.Ph.
Vice President Regulatory Affairs and Compliance
1500 21st Avenue South, Suite 310
Nashville, TN 37212

Dear Mr. Cipriano:

Reference is made to your orphan drug application of November 30, 1993 submitted pursuant to section 526 of the Federal Food, Drug, and Cosmetic Act for the designation of CroTab™ (polyvalent crotalid antivenin, ovine, Fab) as an orphan drug (application #93-789).

We have completed the review of this application and have determined that polyvalent crotalid antivenin, ovine, Fab qualifies for orphan designation for the treatment of envenomations inflicted by North American crotalid snakes. Please note that it is polyvalent crotalid antivenin, ovine, Fab and not its formulation that has received orphan designation.

Prior to marketing approval, sponsors of designated orphan products are requested to submit written notification to this Office of their intention to exercise orphan drug exclusivity if they are the first sponsor to obtain such approval for the drug. This notification will assist FDA in assuring that approval for the marketing of the same drug is not granted to another firm for the statutory period of exclusivity. Also please be advised that if polyvalent crotalid antivenin, ovine, Fab were approved for an indication broader than the orphan designation, your product might not be entitled to exclusive marketing rights pursuant to Section 527 of the FFDCA. Therefore, prior to final marketing approval, sponsors of designated orphan products are requested to compare the designated orphan indication with the proposed marketing indication and to submit additional data to amend their orphan designation prior to marketing approval if warranted.

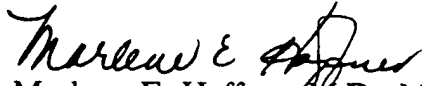
In addition, please inform this office annually as to the status of the development program, and at such time as a marketing application is submitted to the FDA for the use of polyvalent crotalid antivenin, ovine, Fab as designated. If you need further assistance in the development of your product for marketing, please feel free to contact Mr. Peter Vaccari at (301) 443-4718.

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Please refer to this letter as official notification of designation and congratulations on obtaining your orphan drug designation.

Sincerely yours,



Marlene E. Haffner, M.D., M.P.H.
Director



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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CONFIDENTIAL

A. J. Kazimi
Chief Operating Officer
Therapeutic Antibodies, Inc.
1500 21st Avenue South, Suite 310
Nashville, TN 37212

Reference: FD-R-000945-01-1

Dear Mr. Kazimi:

Enclosed is a revised Notice of Grant Award (NGA) for the above referenced grant project entitled "Clinical Trial of Polyspecific Crotalid Antivenin." Based on the justification provided in your letter dated October 28, 1993, all Special Terms and Conditions have been lifted.

PHS policy requires that you be informed that the DHHS Inspector General maintains a toll free telephone number (800/368-5779) for receiving information concerning fraud, waste and abuse under grants and cooperative agreements. Such reports will be kept confidential and callers may decline to give their names if they choose to remain anonymous.

If you have any questions concerning this action, please contact Ms. Maura Stephanos at (301) 443-6170.

Sincerely yours,

Robert L. Robins
Chief, Grants and Assistance
Agreements Section, SCAAB, DCGM

Enclosure

cc: Dr. Richard Dart, Principal Investigator
Rocky Mountain Poison Center
645 Bannock Street
Denver, CO 80204

1. DATE ISSUED (Mo/Day/Yr) 26/9/1993		2. CFDA NO. 93.103	
3. SUPERSEDES AWARD NOTICE dated 9/29/93 except that any additions or restrictions previously imposed remain in effect unless specifically rescinded.			
4. GRANT NO. FD-R-000945-01-1		5. ADMINISTRATIVE CODES FD-R01-6-O	
Formerly:			
5. PROJECT PERIOD Mo/Day/Yr. From 9/30/93 Through 9/29/94		6. BUDGET PERIOD Mo/Day/Yr. From 9/30/93 Through 9/29/94	

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
Food and Drug Administration
REVISION

NOTICE OF GRANT AWARD
AUTHORIZATION (Legislation/Regulation)

ORPHAN PRODUCTS DEVELOPMENT
Section 301 of the PHS Act (42 USC 241)

6. TITLE OF PROJECT (OR PROGRAM) (Limit to 56 spaces) Clinical Trial of Polyspecific Crotalid Antivenin	
9. GRANTEE NAME AND ADDRESS a. Therapeutic Antibodies, Inc. c. 1500 21st Avenue South, Suite 310 d. Nashville TN 37212	
10. DIRECTOR OF PROJECT (PROGRAM DIRECTOR/PRINCIPAL INVESTIGATOR) (LAST NAME FIRST AND ADDRESS) Dart, Richard Rocky Mountain Poison Center 645 Bannock Street Denver, CO 80204	

11. APPROVED BUDGET (Excludes PHS Direct Assistance)		12. AWARD COMPUTATION FOR FINANCIAL ASSISTANCE	
I PHS Grant Funds Only		a. Amount of PHS Financial Assistance (from Item 11.u.) \$ 99,42	
II Total project costs including grant funds and all other financial participation (Select one and place NUMERAL in box.) I		b. Less Unobligated Balance From Prior Budget Periods \$	
a. Salaries and Wages \$ 24,550		c. Less Cumulative Prior Award(s) This Budget Period \$ 99,42	
b. Fringe Benefits \$ 5,072		d. AMOUNT OF FINANCIAL ASSISTANCE THIS ACTION \$	
c. Total Personnel Costs \$ 29,622		13. RECOMMENDED FUTURE SUPPORT (SUBJECT TO THE AVAILABILITY OF FUNDS AND SATISFACTORY PROGRESS OF THE PROJECT):	
d. Consultant Costs \$ 0		YEAR TOTAL DIRECT COSTS / STIPENDS YEAR TOTAL DIRECT COSTS / STIPENDS	
e. Equipment \$ 0		a. 02 \$ \$0 d.	
f. Supplies \$ 0		b. e.	
g. Travel \$ 10,000		c. f.	
h. Patient Care—Inpatient \$ 0		14. APPROVED DIRECT ASSISTANCE BUDGET (IN LIEU OF CASH):	
i. —Outpatient \$ 0		a. Amount of PHS Financial Assistance \$	
j. Alterations and Renovations \$ 0		b. Less Unobligated Balance From Prior Budget Periods \$	
k. Other \$ 0		c. Less Cumulative Prior Award(s) This Budget Period \$	
l. Consortium/Contractual Costs \$ 59,800		d. AMOUNT OF FINANCIAL ASSISTANCE THIS ACTION \$	
m. Trainee Related Expenses \$ 0		15. PROGRAM INCOME SUBJECT TO 45 CFR PART 74, SUBPART F, OR 45 CFR 92.25, SHALL BE USED IN ACCORD WITH ONE OF THE FOLLOWING ALTERNATIVES: (Select One and Place LETTER in box.)	
n. Trainee Stipends \$ 0		a. DEDUCTION	
o. Trainee Tuition and Fees \$ 0		b. ADDITIONAL COSTS	
p. Trainee Travel \$ 0		c. MATCHING a.	
q. TOTAL DIRECT COSTS \$ 99,422		d. OTHER RESEARCH (Add / Deduct Option)	
r. INDIRECT COSTS (Rate 0 % of SAWTADC) \$ 0		e. OTHER (See REMARKS)	
s. TOTAL APPROVED BUDGET \$ 99,422		16. THIS AWARD IS BASED ON AN APPLICATION SUBMITTED TO, AND AS APPROVED BY, THE PHS ON THE ABOVE TITLE PROJECT AND IS SUBJECT TO THE TERMS AND CONDITIONS INCORPORATED EITHER DIRECTLY OR BY REFERENCE IN THE FOLLOWING:	
t. SBIR Fee \$ 0		a. The grant program legislation cited above. b. The grant program regulation cited above.	
u. Federal Share \$ 99,422		c. This award notice including terms and conditions, if any, noted below under REMARKS.	
v. Non-Federal Share \$ 0		d. PHS Grants Policy Statement including addends in effect as of the beginning date of the budget period	
		e. 45 CFR Part 74 or 45 CFR Part 92 as applicable.	

REMARKS: (Other Terms and Conditions Attached — ☒ Yes ☐ No)

This revised award is issued to lift all Special Terms and Conditions.

PHS GRANTS MANAGEMENT OFFICER: (Signature) R. L. Robins		(Name-Typed/Print) Robert L. Robins, Grants Management Officer		(Title)	
17. OBJ. CLASS. 41.41		18. CRS - EN 1621212485A1		19. LIST NO.: FD-17-94	
FY-CAN 3-6990114-W-1965		DOCUMENT NO. b. Appro. 7530600		ADMINISTRATIVE CODE c. FDR01	
21. a.		b. PMS #22320Q-10		d. \$0	
22. a.		c. a. 06-000000945A		e. \$0	

GRANT PAYMENT INFORMATION
NOTE APPROPRIATE PAYMENT SYSTEM CHECKED BELOW

1. (X) Payments under this award will be made available through the DHHS Payment Management System (PMS). PMS is administered by the Division of Payment Management (DPM), Office of the Deputy Assistant Secretary, Finance, which will forward instructions for obtaining payments. Inquiries regarding payments should be directed to:

Division of Payment Management
DHHS/PHS/OASH/OM/ORM/DPM
P.O. Box 6021
Rockville, MD 20852
Telephone Number: (301) 443-1660

2. () Payments under this award will be made available through the Accounting and Indirect Cost Section, Federal Assistance Accounting Branch of the National Institutes of Health. Inquiries regarding payment should be directed to:

Accounting and Indirect Cost Section
Federal Assistance Accounting Branch
National Institutes of Health
Building 31, Room B1B04
9000 Rockville Pike
Bethesda, MD 20892
Telephone Number: (301) 496-5635

3. () Payments under this award will be made available through the Grants Section, General Accounting Branch of the Health Resources and Services Administration. Inquiries regarding payment should be directed to:

Grants Section, General Accounting Branch
Health Resources and Services Administration
Parklawn Building, Room 16-23
5600 Fishers Lane
Rockville, MD 20857
Telephone Number: (301) 443-1464

4. ()

The HHS Inspector General maintains a toll-free hotline for receiving information concerning fraud, waste, or abuse under grants and cooperative agreements. Such reports are kept confidential and callers may decline to give their names if they choose to remain anonymous. The numbers are:

(If caller is inside Maryland)	1-800-638-3986
(If caller is outside of Maryland)	1-800-368-5779

The mailing address is:

HHS, OIG Hotline
P.O. Box 17303
Baltimore, MD 21203-7303

NOTICE OF GRANT AWARD (Continuation Sheet)

PAGE 2 of 2	DATE ISSUED (Mo./Day/Yr.) JUN 26 1994
GRANT NO. FD-R-000945-01-1	

ITEM NO.

TERMS AND CONDITIONS:

Reporting Requirements

1. Quarterly program monitoring will be conducted which may be in the form of telephone conversations between the Principal Investigator and the Project Officer/Grants Management Specialist. Program monitoring may also be in the form of site visits.
2. Financial Status Reports (SF-269) and Program Progress Reports are required quarterly accordingly to the following schedule:

Quarter	Reporting Period	Reports Due
1st	10/01/93-12/31/93	01/31/94
2nd	01/01/94-03/31/94	04/30/94
3rd	04/01/94-06/30/94	07/31/94
4th	07/01/94-09/29/94	10/31/94

A Final Financial Status Report, Final Program Progress Report and an Invention Statement are due 12/31/94. These forms will be mailed to the Principal Investigator by the Grants Management Specialist.

An original and two copies of these reports must be submitted to the FDA Grants Management Officer by the due dates.

SPECIAL TERMS AND CONDITIONS:

1. This term and condition is lifted.
2. This term and condition is lifted.
3. This term and condition is lifted